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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,260	03/26/2001	Nicholas J. Schork	GENSET.076C1	9223

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EXAMINER

KENEDY, ANDREW A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/818,260

Applicant(s)

SCHORK ET AL.

Examiner

Andrew A. Kenedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7 and 40-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7 and 40-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/5/2004
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Cancellation of original Claims 2, 3, 5, 6 and 8-39, amendment of original Claims 1, 4 and 7, and addition of new Claims 40-50 in the response filed on March 2, 2004, is acknowledged. Applicants' arguments in the response have been fully considered.

The following rejections and/or objections are either reiterated or newly applied, and constitute the complete set presently being applied to pending Claims 1, 4, 7 and 40-50.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The previous rejection of Claim 1 under 35 U.S.C. 101 is hereby withdrawn based on the introduction of physical manipulation steps into the method.

The previous rejection of Claim 4 under 35 U.S.C. 101 is hereby withdrawn based on the introduction of systems having hardware implementation limitations.

Specification

Applicants' previous submission of a preliminary amendment filed on March 17, 2003, which amended the specification to include a complete statement of claimed priority, is acknowledged and has been entered. Therefore, the examiner's previous objection regarding the lack of a complete priority statement in the specification is hereby withdrawn.

Claims

Amended Claim 1 has the term "profiles" deleted from the claim preamble, but does not indicate the deletion in compliance with the requirements of 37 CFR 1.121(c). As a result, the Examiner is uncertain whether the deletion is a typographical error or intentional.

Amended Claim 1 requires "a least two groups" which appears to be a grammatical misspelling of the phrase "at least two groups".

Claim Rejections - 35 USC § 112

Claims 1, 4, 7 and 40-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 40-42 and 50 are drawn to methods that include newly added first and second steps requiring "obtaining and assigning haplotypes". Applicant has not pointed to the basis for these new limitations, and none is apparent. While the specification discloses a process for "estimation of haplotype frequencies" (see the specification, pg. 20-22), this is neither the same nor commensurate in scope with the newly claimed limitation of "obtaining and assigning haplotypes". Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 4, 7, 46, 47, 48 and 49 require "assign(ing) a binary code to the haplotype". However, the "binary code" that is assigned is not subsequently used by any of the method steps of these claims. While Applicants have disclosed the assignment of "a binary code" in a set convention called a "binary mask array" to haplotypes for use in manipulating the haplotypes and storing information about the haplotypes within the context of determining the statistical significance of a difference between haplotype frequency of at least two groups, Applicants do

not appear to have disclosed or contemplated the assignment of a binary code to haplotypes without subsequent usage (for no purpose). Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 4, 45, 46 and 47 require a "module". Applicants have not previously disclosed the term "module" in the specification or previous claims. Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 4, 45, 46 and 47 require a "programmed storage device". Applicants have not previously disclosed the terminology "programmed storage device" in the specification or previous claims. Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 40-42, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 40, step (e) requires "calculating all possible single-haplotype chi-square tests in order to provide measures of association between groups". This final step does not reach the preamble goal of "determining the statistical significance of a difference between haplotype frequency of at least two groups". It would not be obvious to one of ordinary skill in the art how

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to reach the goal required by the preamble using the claimed method, without additional positive active steps.

Claim 41, step (e) requires "assessing the statistical significance of individual haplotypes using an odds ratio or a P-excess value in order to provide measures of association between groups". This final step does not reach the preamble goal of "determining the statistical significance of a difference between haplotype frequency of at least two groups". It would not be obvious to one of ordinary skill in the art how to reach the goal required by the preamble using the claimed method, without additional positive active steps.

Claim 46 is a system for executing a method requiring a sixth step of "calculating all possible single-haplotype chi-square tests in order to provide measures of association between groups". This final step does not reach the preamble goal of "determining the statistical significance of a difference between haplotype frequency of at least two groups". It would not be obvious to one of ordinary skill in the art how to reach the goal required by the preamble using the claimed method, without additional positive active steps.

Claim 47 is a system for executing a method requiring a sixth step of "assessing the statistical significance of individual haplotypes using an odds ratio or a P-excess value in order to provide measures of association between groups". This final step does not reach the preamble goal of "determining the statistical significance of a difference between haplotype frequency of at least two groups". It would not be obvious to one of ordinary skill in the art how to reach the goal required by the preamble using the claimed method, without additional positive active steps.

Claims 1, 4, 7 and 40-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 7, 40, 41, 46, 47, 48 and 49 were amended to require that haplotypes be assigned "a binary code" or identified by "a binary code". This is confusing since "a binary code" is assigned by computers to all digitized information and then used by the computer to identify that information. It appears that perhaps Applicants intended to mean a binary mask array, but this is not clear from terminology used.

Claims 4, 46 and 47 require "a programmed storage device comprising at least one module or one or more computers". This limitation is confusing since a computer can comprise a programmed storage device, but a programmed storage device cannot comprise a computer in all the forms encompassed by the limitation. For example, some simple or specialized task-dedicated computers simply do not have the ability to function as a storage device. Furthermore, the term "module" is indefinite, thereby rendering the scope of the claim uncertain.

Claims 4, 7, 46, 47, 48 and 49 require "assign(ing) a binary code to the haplotype". It is unclear how and at what step the assigned binary code is to be used in the methods of these claims, since no subsequent step uses the assigned binary code in the methods as claimed.

Claims 4, 43, 44, 45, 46 and 47 all require systems comprising one or more computers for executing methods that comprise multiple steps. In the instance when more than one computer is used as the system, it is unclear how the multiple computers would functionally interact to execute the methods as claimed. Each set of method step (or first, second, third, etc. instructions) could conceivably be executed on a single computer, or as in the case of multiple

computers, each could be executed on different computers, using a separate software program for each step of the method. Applicants have not clearly indicated how the method would be divided among multiple computers and how those computers should functionally interact to properly execute the method.

Claim 42 requires "drawing an inference from any statistical significance". This limitation is indefinite as to what the nature of the "inference" should be, thereby rendering the scope of the claim uncertain.

Claim 50 requires "coding said haplotypes with binary mask arrays". It is unclear why the haplotypes are coded with binary mask arrays since the binary mask arrays are not used in any subsequent step of the method as claimed.

Notice to Applicant

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant is further reminded that deletion of any newly added limitations to the amended claims may result in the reinstatement of previous grounds of rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is (571)-272-0574. The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.K. April 19, 2004

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER 4/19/04

AC1631